

Package leaflet: Information for the user

Panzynorm forte-N 20000IU+12000IU+900IU film-coated tablets **Lipase, amylase, protease**

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must contact your doctor if you do not feel better or if you feel worse

What is in this leaflet

1. What Panzynorm forte-N is and what it is used for
2. What you need to know before you use Panzynorm forte-N
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1. What Panzynorm forte-N forte is and what it is used for

Panzynorm forte-N contains naturally occurring and high activity enzymes produced in pancreas: lipase, amylase and protease. These substances are usually released to the small intestine when we eat and they help to break down and digest different food components. Lipase ensures digestion of dietary fats, amylase breaks down carbohydrates and protease breaks down proteins. The ingredients of Panzynorm forte-N tablets originate from pigs and are extremely similar to the substances present in human body. Tablets are enteric-coated. Therefore, enzymes are released from the tablet only when it reaches the small intestine, where they replace enzymes that the pancreas is unable to produce.

How to use Panzynorm forte-N

Panzynorm forte-N is indicated for treatment of exocrine pancreatic insufficiency and cystic fibrosis (certain gland disorder involving the scarring of the pancreatic ducts).

2. What you need to know before you use Panzynorm forte-N

Do not take Panzynorm forte-N

- if you are allergic to active substances or any of the other ingredients of this medicine (listed in section 6) or pork proteins,
- if you have acute pancreatitis or exacerbation of chronic pancreatitis.

Panzynorm forte-N should not be given to children under 15 years of age with cystic fibrosis.

Warnings and precautions

Children and adolescents

The safety of using this medicine in children under 15 years of age has not been established.

Other medicines and Panzynorm forte-N

Pancreatic enzymes may reduce absorption of folic acid.

Concurrent treatment with H₂-blockers or proton pump inhibitors (medicines to treat peptic ulcer) may

increase the effectiveness of pancreatic enzymes.

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Panzynorm forte-N forte with food and drink

Panzynorm forte-N must be taken at mealtimes with plenty of fluid.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The safety of Panzynorm forte-N during pregnancy and breast-feeding has not been established.

Driving and using machines

Panzynorm forte-N has no effect on the ability to drive or use machines.

Panzynorm forte-N contains lactose

If you have been told by your doctor that you have intolerance to some sugars, consult your doctor before taking this medicine.

3. How to take Panzynorm forte-N

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take Panzynorm forte-N at mealtimes with plenty of liquid. Swallow the tablets whole, do not chew or crush them. Use the lowest dose of this medicine to prevent problems (i.e. you will gain control over the frequency/quantity of stool and your body weight). Start treatment at a dose of 1 tablet during main meals (i.e. three times a day). If you find that this dose is not sufficient, you may increase the dose. A dose of 1-2 tablets during main meals (three times a day) is usually sufficient. You may also take one tablet with other meals if necessary.

If you feel that the effect of **Panzynorm forte-N** is too strong or too weak, talk to your doctor or pharmacist.

The jar contains a sachet of moisture-absorbent substance, do not eat it.

Use in children

The safety of using this medicine in children under 15 years of age has not been studied.

If you take more Panzynorm forte-N than you should

If you have taken too high a dose, consult with your doctor or pharmacist immediately.

It is not known whether overdose leads to systemic toxicity, but taking higher than prescribed doses may cause diarrhoea, tenderness/itching in rectal area and intestinal obstruction. The level of uric acid may increase in the blood and urine.

If you forget to take Panzynorm forte-N

If you forget to take this medicine, take the next dose with your next meal.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects are very rare. If you get any of the symptoms listed below, stop using the medicine and contact your doctor or the nearest hospital immediately: swelling of face, mouth, lips or throat, causing difficulty breathing and swallowing, swelling of hands or feet, rash, fainting or yellowing of the skin, mucosa and whites of the eyes. These symptoms indicate possible severe hypersensitivity reaction, meaning that you need immediate medical attention. If your stomach is bloated, painful or if you have acute abdominal pains, consider the possibility of intestinal obstruction.

Common side effects include nausea, vomiting and abdominal pain, but these symptoms usually do not require discontinuation of using the medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Panzynorm forte-N

Do not use this medicine after the expiry date which is stated on the carton after EXP.

Tablet bottle

Do not store above 25°C.

Store in the original package, protected from humidity.

Blister

This medicinal product does not require any special storage temperature.

Store in the original package, protected from humidity.

Keep this medicine out of the sight and reach of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Panzynorm forte-N contains

- The active substances are lipase, amylase, and protease. One film-coated tablet contains 20 000 units of lipase, 12 000 units of amylase and 900 units of protease.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate, all in the tablet core, and hypromellose, methacrylic acid and ethyl acrylate copolymer, tri-ethyl citrate, titanium oxide, talc, silica-stabilised emulsion, vanillin flavour, bergamot flavour, macrogol 6000, carmellose sodium and polysorbate 80, all in the tablet coating.

What Panzynorm forte-N looks like and contents of the pack

Tablets are white or white-off, round, convex and fragrant. Amber glass bottle (type III) with aluminium cap, desiccant capsule and cotton absorbent contains 10, 30 or 100 tablets.

Blister pack (OPA/Al/PVC-Al-folium): 10, 30 or 100 film-coated tablets in a pack.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d. d., Novo mesto

Šmarješka cesta 6
8501 Novo mesto
Slovenia

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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